[BILLING CODE 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed collection; 60-day comment request

Drug Accountability Report Form and Investigator Registration Procedure in the Conduct of Investigational Trials for the Treatment of Cancer (NCI)

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the Cancer Therapy Evaluation Program (CTEP)/ Division of Cancer Therapy and Diagnostics (DCTD), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Written comments and/or suggestions from the public and affected agencies are invited to address one or more of the following points: (1) Whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) The accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) The quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection

techniques or other forms of information technology.

TO SUBMIT COMMENTS AND FOR FURTHER INFORMATION: To obtain a copy of the data collection plans and instruments, submit comments in writing, or request more information on the proposed project, contact, Charles Hall, RPh, M.S., Chief, Pharmaceutical Management Branch, Cancer Therapy Evaluation Program, National Cancer Institute, 9609 Medical Center Drive, RM 5W240, MSC 9725, Bethesda, Maryland 20892. Or call non-toll-free number (240) 2766575, or e-mail your request, include your address to: hallch@mail.nih.gov.

COMMENT DUE DATE: Comments regarding this information collection are best assured of having their full effect if received within 60 days of the date of this publication.

PROPOSED COLLECTION: Title: Drug Accountability Report Form and Investigator Registration Procedure in the Conduct of Investigational Trials for the Treatment of Cancer, 0925-0613, Expiration Date 03/31/2016, Revision, National Cancer Institute (NCI), National Institutes of Health (NIH).

Need and Use of Information Collection: Revision. The U.S. Food and Drug Administration (FDA) holds the National Cancer Institute (NCI) responsible, as a sponsor of investigational drug trials, for the collection of information about the clinical investigators who participate in these trials and to assure the FDA that systems for accountability are being maintained by investigators in its clinical trials program. The information collected is used to identify qualified investigators and to facilitate the submission and distribution of important information relative to the investigational drug and the response of the patient to that drug.

Investigators are physicians who specialize in the treatment of patients with cancer. Data obtained from the Drug Accountability Record is used to track the dispensing of investigational anticancer agents from receipt from the NCI to dispensing or administration to patients. NCI and/or its auditors use this information for compliance purposes. The frequency of Response is up to 16 times per year. The affected public is private sector including businesses, other for-profit organizations, and non-profit institutions. The type of respondents are investigators, pharmacists, nurses, pharmacy technicians, and data managers.

OMB approval is requested for 3 years. There are no capital costs, operating costs or maintenance costs. The total estimated annualized burden hours are 22,645 hours.

Estimated Annualized Burden Hours

Table 1 Estimates of Annual Burden

Type of Respondents	Form	Number of Respondents	Frequency of Response	Average Time per Response (in Hours)	Total Hour Burden
Investigators and Designee for Investigator Registration and DARF	Statement of Investigator (Attachments 3A, 3B or 10)	22,283	1	15/60	5,571
	NCI/DCTD/CTEP Supplemental Investigator (Attachment 4)	22,283	1	10/60	3,721
	Financial Disclosure Forms (Attachment 5A or 5B)	22,283	1	5/60	1,849
	NCI/DCTD/CTEP Drug Accountability Record Form (DARF and DARF-Oral) (Attachments 1 & 2)	3,288	16	4/60	3,525

Dated: November 9, 2015.

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